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REPORT
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SACCHARIN STUDY AND LABELING ACT AMENDMENTS OF 1985

APRIL 22 (legislative day, APRIL 15), 1985.—Ordered to be printed

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Mr. HATCH, from the Committee on Labor and Human Resources, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 484]

The Committee on Labor and Human Resources, to which was referred the bill (S. 484) to amend the Saccharin Study and Labeling Act, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

I. SUMMARY OF LEGISLATION

S. 484 as reported from Committee further amends section 3 of the Saccharin Study and Labeling Act (Public Law 95-203 as amended by Public Law 96-273, Public Law 97-42, and Public Law 98-22) to extend to "May 1, 1987," certain limitations on actions by the Secretary of Health and Human Services respecting saccharin.

II. BACKGROUND AND NEED FOR LEGISLATION

The current law, section 3 of Public Law 95-203 as amended, expires April 22, 1985. In pertinent part it provides that the Food and Drug Administration may not move administratively against saccharin solely on the basis of pre-1978 studies or data. Since that time a number of additional studies have been performed, and others are planned or in progress, but none have satisfactorily answered the central question of whether saccharin is a public health risk. In view of the fact that saccharin has been used for some

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ninety years and has never been causally linked to human injury and meets needs of individuals needing sugar substitutes, it is appropriate to continue the current limited moratorium.

III. Text of S. 484 As Reported

A BILL To amend the Saccharin Study and Labeling Act

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 3 of the Saccharin Study and Labeling Act (21 U.S.C. 348 nt.) is amended by striking out "During the period beginning on the date of the enactment of this Act and ending twenty-four months after the date of enactment of the Saccharin Study and Labeling Act Amendment of 1983"and inserting in lieu thereof "During the period ending May 1, [1988] *1987*".

IV. History of S. 484 Including Hearings

S. 484 was introduced on February 20, 1985 by Senator Orrin G. Hatch and was referred to the Committee on Labor and Human Resources.

A public hearing on the bill was held on April 2, 1985 before the full Committee. Testimony was heard from:

Dr. Frank Young, Commissioner, U.S. Food and Drug Administration, accompanied by Mr. Thomas Scarlett, Esq., Dr. Sanford Miller and Dr. Gary Flamm

Dr. Jerry Schoenig, Annapolis, Maryland

Dr. Ronald Hart, Director, National Center for Toxicological Research (FDA), Litle Rock, Arkansas

Dr. Douglas Arnold, Toxicology Research Division, Health Protection Branch, Health and Welfare Canada, Ottawa

Dr. Frederick Trowbridge, National Centers for Disease Control, Atlanta, Ga.

Dr. Richard Wurtman, Professor of Neuroendocrine Regulation, Massachusetts Institute of Technology, Cambridge, Mass.

Dr. Lewis Stegink, Department of Pediatrics and Biochemistry, College of Medicine, University of Iowa, Iowa City

Dr. Ronald Arky, Chief of Medicine, Mt. Auburn Hospital, Cambridge, Mass.; representing the American Diabetes Association

Dr. Howard Roberts, Vice President, National Soft Drink Association, Washington, D.C.

Dr. Michael Jacobson, Center for Science in the Public Interest, Washington, D.C.

Written testimony was also submitted by a number of individuals and organizations.

On April 17, 1985, the Committee met in open executive session to consider the bill. The Committee agreed, without objection, to shorten the extension period from three years to two. An amendment by Senator Metzenbaum to require quantitative aspartame labeling was defeated. The bill as amended was ordered reported favorably to the Senate.

V. Committee Views

The Saccharin Study and Labeling Act was enacted in 1978 in response to a proposal by the Food and Drug Administration to remove saccharin from the market. This proposal followed a study report implicating saccharin in increased bladder tumor incidence in rats. At that time saccharin had been in use as an artificial sweetener for over eighty years and had never been causally linked to any illness or death in humans. It was an important factor in the physical and emotional health of diabetics and others who need to control their weight or caloric intake.

The F.D.A. proposal prompted considerable Congressional interest. After pursuing its own inquiry, Congress felt that the evidence at that time was insufficient to conclude that saccharin was a significant health risk in humans, and found that it conferred real benefits on a significant portion of the population. Congress' response was the Saccharin Study and Labeling Act, which forbade. F.D.A. from moving against saccharin solely on the basis of data available when it was enacted. This step clearly conveyed to F.D.A. Congress intent that the agency have more solid and substantial evidence of a human health risk before it restricted or eliminated the use of the sweetener.

However, acknowledging the questions which had been raised, the Act also mandated notices and warning labels on products containing saccharin in order to advise the public that there might be some risk involved in consumption of the product. Provisions of the Act addressed the display and prominence of these labels. A member of the Committee, Senator Howard Metzenbaum, has raised questions on whether current labeling practices satisfy the requirements and intent of this law. The Committee therefore requests that F.D.A. review the compliance of labels with law generally and also the efficacy of the labels (focused on consumer awareness, not on amounts consumed) and promptly report back to the Committee.

In the Act and its amendments, Congress also directed F.D.A. to provide for studies designed to resolve the doubts about saccharin's safety. Since the Committee last approved legislation extending the Act, additional studies have been completed, without, however, completely resolving the central safety question. No scientist at the hearing on the bill felt that saccharin has been demonstrated to be a significant human health risk or that the current evidence warranted its removal from the market. There was consensus that further studies are advisable; and indeed such studies are currently underway. Thus in all essential respects the conditions leading Congress to pass the Act in 1978 and to extend it on three subsequent occasions still persist. No evidence has yet come forth that saccharin is a carcinogen in humans, despite an unusually long marketing history. And its importance to the health of diabetics and others, while somewhat diminished in several applications by the availability of aspartame, remains significant.

Therefore, the Committee feels it appropriate to extend the current limited moratorium on agency action against saccharin for an additional two years. While that time will likely not be sufficient to

develop the evidence and alternatives which will allow us to make a final determination, it will bring us markedly closer to that goal.

The Committee's inquiry in the current extension process has focused on two areas: the status of the science on saccharin and the availability of alternatives.

Since the enactment of the last extension, two major studies have been completed and are under review at F.D.A. One was conducted within F.D.A. at the National Center for Toxicological Research (NCTR). The other was conducted by the International Research and Development Corporation (IRDC).

The NCTR study confirmed that saccharin introduced directly into the bladder of rats in very high concentrations does increase bladder tumor production in male rats (though not female rats). However, it found that saccharin acts as a cancer inhibitor in mice. Its investigations designed to identify the effect of saccharin in human cell cultures produced inconclusive results. The director of the Center, Dr. Ronald Hart, testified:

> So now we have a situation where we have one species [of rats] which is insensitive, one species [of mouse] which is refractory, and man seems to be acting by a different set of circumstances than either of the other two species, and it is extremely difficult under those circumstances to extrapolate animal data to human health effects.

To attempt to clarify saccharin's mechanism of action and its possible effects in humans, NCTR is pursuing two additional studies, one which is on a twelve to eighteen month timetable and one which will take two and a half years. The Committee welcomes these studies, recognizing the significance of both to the safety issue, as it welcomes others in progress, such as that by the International Life Sciences Saccharin Committee.

The IRDC study established a dose-response curve relating saccharin doses to tumor production in male rats. While there is some difference among scientists over the background rate against which the 1 percent level (equivalent to 250 cans of diet soda per day) should be compared, it appears that the increase of tumors at that level, the lowest studies, may not be statistically significant. This implies a considerable safety margin at foreseeable consumption levels. This study also well demonstrate that the increase in tumors in male rats is directly proportional to the dose or amount of saccharin injected in the laboratory animals.

These two major studies tend to reinforce the conclusion that if saccharin poses any human threat, it is minimal.[1] Dr. Frank Young, Commissioner of the Food and Drug Administration testified:

> In conclusion, therefore, as in the past, we still do not adequately know the answer to all of the questions and un-

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[1] Dr. Gary Flamm of the Food and Drug Administration testified: "I think what is really at issue here is really the mechanism by which saccharin causes cancer in rats and what the implications are to humans. I think our state of ignorance is somewhat similar to what it was in 1977 relative to what the implications truly are. But the one thing that we have managed to do is to show through these epidemiologic studies that you have heard about that saccharin consumption clearly has not been a significant risk factor in bladder cancer among people living in the United States."

certanties giving rise to the original 1977 saccharin moratorium. The actual risk, if any, of saccharin to humans still appears to be slight, however.

The 1980's have seen the emergence of aspertame as an alternative to saccharin in many applications. However, it is not a complete substitute in that it cannot be metabolized, and therefore utilized by a small portion of the population; and it is not as stable as saccharin. Thus it is unsuitble for use where it must be cooked or heat processed or where long shelf life is desirable. Further, it cannot be used in some pharmaceutical and cosmetic applications. Nevertheless, the rapid increase in the use of aspartame has significantly reduced the consumption of saccharin and has served to further minimize any risk from the latter.

Some time was spent at the hearing on S. 484 in the discussion of issues related to aspartame. In markup, the Committee considered, but rejected, an amendment on aspartame offered by Senator Metzenbaum. The amendment would have mandated that soft drinks (and no other category of product) bear a label statement of the amount of aspartame in each container. The committee did not adopt the amendment because the hearing record did not demonstrate any need to single out aspartame and/or soft drinks for treatment different from that for food ingredients and types of foods generally. Moreover, FDA testified at the hearing that it already has the general authority to require such labeling. Dr. Young stated that FDA has never been asked to exercise that authority and thus has had no opportunity to even consider the issue. The Committee feels it premature for Congress to act under these circumstances.

Aspartame is a low-calorie sweetener composed of two amino acids, phenylalanine and aspartic acid, both of which are also found in meats, eggs, fish, grains and other sources of protein. It was first approved by the FDA in 1981, after extensive review and examination of comprhensive studies in animals and numerous clinical studies. Aspartame is not only approved as safe for use in the United States, but has been approved by the World Health Organization, the European Economic Community and by the regulatory agencies of over forty countries.

Brief testimony was received on aspartame during the Committee's hearing on the saccharin bill. Indeed, the subject of quantitative labeling of aspartame only arose by virtue of a suggestion contained in the testimony of a single witness who also testified that he had not asked FDA to exercise its authority to require the labeling.

Two principal arguments were put forward to support the unusual amendment to require that the quantity (as opposed to the identity or name already required by current law) of an ingredient be listed on the labels of only one class of food products. The first argument relates to the overall safety of the amount of aspartame which consumers might ingest. This argument, however, seems based on a misunderstanding of the scientific data and underlying concepts used to set safe consumption levels. The second argument is based on a single scientist's hypothesis and not on any generally accepted scientific fact.

In order to evaluate the safety of a substance for use in food, FDA requires estimates of its probable consumption to be made. Such estimates were made in the case of aspartame. These estimates are based on very conservative assumptions about consumption to ensure that the estimated daily intake (EDI) of a substance is not underestimated.

In the case of aspartame, it was estimated that if aspartame replaced all the sugar and saccharin in the diet, the 99th percentile of projected consumption of aspartame would be 34 milligrams per kilogram of body weight each day (34 mg/kg/day). This conservatively-derived estimate of maximum daily intake was then compared to the acceptable daily intake (ADI).

The ADI for a substance is based on an evaluation of studies in animals and when available, in humans as well. In the case of aspartame, both extensive animal testing and human clinical studies were used to calculate the ADI. The ADI is a conservative upper limit on the amount of a substance that can safely be consumed on a chronic or lifetime basis. It is not unusual nor unsafe for a person to consume more than the ADI on occasion.

The ADI for aspartame set by FDA and reevaluated and reaffirmed several times is 50 mg/kg of body weight. This ADI is based on a broad array of data, including clinical studies in which human volunteers received, with no ill effect, up to 200 mg/kg per day of aspartame, which is equivalent to approximately 5 pounds of sugar per day. Aspartame is judged to be safe for use because the estimate of maximum daily intake, 34 mg/kg/day, is substantially below the acceptable daily intake of 50 mg/kg/day.

Since the approval of aspartame, the actual use has been carefully monitored. Consumption levels for all age groups, including 2–5-year-old children, remain well below the ADI of 50 mg/kg/day. An amendment to require quantitative labeling of aspartame for soft drinks cannot be justified, therefore, by alleging that consumers need to monitor precisely their consumption of aspartame. Moreover, for consumers who wish to know the quantity of aspartame in soft drinks, testimony was received that this information is readily available from both the National Soft Drink Association and from its individual member companies.

The second rationale for the aspartame amendment relates to a scientific hypothesis first put forward two years ago by Dr. Richard Wurtman of MIT. Dr. Wurtman's hypothesis, based on limited studies in rats, is that consumption of large quantities of aspartame together with carbohydrates might result in changes in neurotransmitter activity in the brain, and, therefore, in behavior.

Dr. Wurtman's hypothesis has been reviewed by the FDA which concluded that "the ingestion of aspartame, either alone or in combination with high levels of carbohydrates, will not result in behavioral modification. . . ." (— Federal Register —, July 8, 1983).

The hypothesis was later reviewed by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment of the Department of Health and Social Security in the United Kingdom, which stated "categorically" that it saw:

> no reason to change its previous conclusion about the safety of aspartame. After ingestion, aspartame is broken

> down to phenylalanine and aspartic acid: both are naturally occurring amino acids, and phenylalanine is essential to life. Evidence available shows that the use of aspartame as a sweetener does not raise levels of phenylalanine in the body significantly above the values seen when normal foods containing phenylalanine are consumed; it is therefore most unlikely that aspartame would have any effects on humans that would not be seen with common foodstuffs.

Most recently, Dr. Wurtman's hypothesis was considered by the Scientific Committee for Foods of the European Economic Community, which concluded that:

> The data provided no evidence that the occasional transient changes in blood amino acid levels, following simultaneous ingestion of aspartame and glucose, could produce changes in neurotransmitter levels which might affect mood or behaviour.

I short, Dr. Wurtman's hypothesis has been carefully considered by leading independence scientific review authorities and, on the basis of currently available data has not been confirmed. Many ordinary foods and food constituents, including sugar itself and other amino acids of protein, can alter the amino acid composition of the brain of laboratory rats. These changes are not abnormal nor potentially dangerous. Rather, such changes are expected and normal after the ingestion of foods.

Despite its confidence in the safety of aspartame, FDA in February of 1984 requested the Centers for Disease Control to revise some 600 user conplaints which it had received. That study was conpleted last fall.

Dr. Frederick Trowbridge of CDC testified as follows:

> We found, in summary, that no specific constellation of symptoms clearly related to aspartame consumption was identified. Despire great variety overall, the majority of frequently reported symptoms were mild and are symptoms that are common in the general populace.
>
> While some reports are undoubtedly due to the coincidence of symptoms and aspartame consumption, and others may be due to the suggestibility of some persons, still others may be attributable to some as yet undefined sensitivity of individuals to aspartame in commonly consumed amounts, and the only way that these possibilities can be thoroughly evaluated would be through focused clinical studies.

Contained in the CDC report itself is a further elaboration: [I]t would seem that the higest priority for any future investigation might be in the neurological behavioral area, focusing on such symptoms as headaches, mood alterations, and behavior changes.

The Committee is concerned that such studies take place. Testimony was heard from Dr. Young and Dr. Miller that one such study is being planned and will be carried out at Duke University

Medical School. The Committee directs the F.D.A. to review and follow up on the C.D.C. recommendations on an expedited basis.

Saccharin and aspartame are the only two artificial sweeteners approved for general use in the United States. Numerous witnesses, Dr. Young in particular, emphasized the desirability of maintaining at least two alternatives on the market, since the presence of both reduces the quantity of either that would otherwise be consumed. Other sweeteners, including cyclamates and acesulfame-K, are currently under review and testing at F.D.A., and it is to be hoped that in time they will be found safe and approved. However, F.D.A. testified that it will be close to three years before action can be expected on either.

In this connection, the Committee commends F.D.A. for its reexamination of the data on cyclamates in light of current scientific knowledge and analytical techniques. While expressing no opinion on whether or not cyclamates should be returned to the market, the Committee notes that regulatory judgments are necessarily based on the best science available at the time of the judgment. In the event science advances, as it often will, in ways that cast doubt on earlier analyses or interpretations of data, or on the data themselves, it is appropriate for the agency to revisit its earlier conclusions, whether the result it to return to the market substances which have been removed or to remove from the market some which may have been approved.

In conclusion, the Committee does not intend its action extending the saccharin moratorium to be interpreted as an endorsement of the finality of past studies on the issue of saccharin's safety. While further, necessary studies are underway, the Committee recognizes that many people, including diabetics and others on specific diets, want a no-calorie or low-calorie substitute for sugar and that at the present time saccharin remains one of the only two such substances approved for general use, and the only one available for all uses. The Committee also hopes that vigorous efforts to develop additional sweetners will continue.

Finally, the Committee notes as it did in its report on the last extension, that should information come available during the next two years demonstrating a public health risk from continued use of saccharin, under S. 484 the F.D.A. retains the authority to take regulatory action.

VI. Tabulation of Votes Cast in Committee

The Committee met to consider the bill in open executive session on April 17, 1985. An amendment by Senator Metzenbaum to require quantitative aspartame labeling was rejected by a vote of 7 to 9, as follows:

Aye (7)	Nay (9)
Kennedy	Hatch
Pell	Stafford
Metzenbaum	Quayle
Matsunaga	Nickles
Dodd	Hawkins

Simon	Thurmond
Kerry	Weicker
	Wallop
	Grassley

The bill as amended was ordered reported to the Senate without objection.

VII. Regulatory Impact Statement

Since the effect of the bill is solely to continue the limited moratorium on agency action against saccharin, the Committee has determined that this bill will not increase the regulatory burden and paperwork.

VIII. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, April 19, 1985.

Hon. Orrin G. Hatch,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has reviewed S. 484, a bill to amend the Saccharin Study and Labeling Act, as ordered reported by the Senate Committee on Labor and Human Resources on April 17, 1985.

Under the Act, the Secretary of Health and Human Services may not restrict the distribution of saccharin or products that contain saccharin solely on the basis of studies that were completed before enactment and show saccharin's carcinogenic effects. S. 484 would extend this moratorium to May 1, 1987.

It is expected that the budgets of the federal government or of state and local governments would not increase as a result of enactment of this legislation.

With best wishes,
Sincerely,

Rudolph G. Penner, *Director.*

IX. Family Fairness Statement

The Committee has determined that this bill has a modestly favorable impact on the family. By helping assure the availability during the next two years of saccharin, an artificial sweetener, it will positively affect the families of those who are diabetics or who are concerned about limiting their weight.

X. Section-by-Section Analysis

The bill contains only one section, which amends section 3 of the Saccharin Study and Labeling Act (Public Law 95-203 as amended by Public Law 96-273, Public Law 97-42, and Public Law 98-22) to extend certain limitation on actions affecting Saccharin by the Secretary of Health and Human Service through the period "ending May 1, 1987."

XI. Changes in Existing Law

In compliance with rule XXVI, paragraph 12, of the Standard Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Section 3 of the Saccharin Study and Labeling Act

Sec. 3. [During the period beginning on the date of the enactment of this act and ending twenty-four months after the date of enactment of the Saccharin Study and Labeling Act Amendment of 1983,] *During the period ending May 1, 1987,* the Secretary—

(1) may not amend or revoke the interim food additive regulation of the Food and Drug Administration of the Department of Health, Education, and Welfare applicable to saccharin and published on March 15, 1977 (section 180.37 of part 180, subchapter B, chapter 1, title 21, Code of Federal Regulations (42 Fed. Reg. 14638)), or

(2) may, except as provided in section 4 and the amendments made by such section, not take any other action under the Federal Food, Drug, and Cosmetic Act to prohibit or restrict the sale or distribution of saccharin, any food permitted by such interim food additive regulation to contain saccharin, or any drug or cosmetic containing saccharin, solely on the basis of the carcinogenic or other toxic effect of saccharin as determined by any study made available to the Secretary before the date of enactment of this Act which involved human studies or animal testing, or both.

XII. ADDITIONAL VIEWS OF SENATOR HOWARD M. METZENBAUM

On April 2, the Labor Committee held an extensive hearing on three low-calorie, non-nutritive sweeteners: saccharin, aspartame (NutraSweet) and cyclamate. The hearing was held to assist the Committee in its deliberations on S.484, a bill to amend the Saccharin Study and Labeling Act.

It was clear from the outset that the issues of science and safety surrounding the three sweeteners were inextricably entwined. The justification for the mortorium on the saccharin ban proposed by the FDA in 1977 had always been the fact that there were no substitutes for saccharin's principal uses. Since the introduction of aspartame (NutraSweet) in 1981, and its approval for use in soft drinks in 1983, that situation has clearly changed. The FDA's current review of cyclamate is also a key component of the artificial sweetener "equation" and one more reason that it is impossible to consider in isolation the issues of health and safety surrounding these substances.

As a result of the hearing, a number of issues became clear. First, regarding saccharin:

—In 1977, the FDA estimated that saccharin could cause up to 1,200 additional cases of bladder cancer a year, assuming everyone in the U.S. consumed the saccharin equivalent of one diet soda a day. The FDA still stands by that assessment.

—Two recent studies on saccharin as a carcinogen and a co-carcinogen (or cancer promoter) show the substance produces tumors in the rat at lower doses than those in the 1977 tests. The FDA used these 1977 tests to justify its proposed ban on saccharin as a food additive.

—The Canadian government has seen no new evidence to cause it to reconsider its decision in 1977 to ban saccharin as a food additive in foods and soft drinks.

—If the current saccharin legislation lapsed for a period of time, the product would remain on the market. The FDA Commissioner testified that, "with the most rapid action, it is 180 days to a year" before any action would be taken to remove saccharin from the market.

—The original Saccharin Information and Labeling Act required warnings on products containing saccharin. These warnings cite the link between saccharin and cancer in laboratory animals. The law states:

> Such statement shall be located in a conspicuous place on such label, and labeling as proximate as possible to the name of such food shall appear in conspicuous and legible type in contrast by typography, layout, and color with other printed matter.

It is clear that this provision of the law is being ignored. Report language accompanying this bill directs the FDA to examine the efficacy of these warnings and report to Congress on how the law is being obeyed.

Regarding cyclamate, the FDA is currently undertaking a review of the carcinogenicity of this substance. Concern had been expressed that the FDA was not going to give full consideration to other problems associated with cyclamate, i.e., testicular atrophy and genetic damage. The FDA Commissioner testified that the FDA intends to examine these issues fully and that it could be up to three years before any decision is made.

In addition, a number of concerns regarding aspartame (NutraSweet) were raised at the hearing on April 2. In July, 1984, Common Cause published an extensive investigative report on the manner in which the FDA approved aspartame. The highlights of that report include the following:

—In 1977, the FDA recommended that Searle be brought before a grand jury for fraudulent tests including tests on aspartame.

—The FDA Commissioner in office when aspartame was approved rejected the findings of a Scientific Board of Inquiry that recommended that aspartame not be approved pending further tests on brain tumors.

—The FDA Commissioner's own in-house team of scientists split on the issue of aspartame approval. Three of the six scientists recommended against approval.

Those who say there is no reason to be concerned about the safety of NutraSweet point to a recent study of consumer complaints carried out by the Center for Disease Control. Though the CDC concluded that the consumer complaints provided no cause for removing NutraSweet from the market, they did suggest further studies in their report:

> The number of instances of persons challenging themselves several times with aspartame-containing products and reporting symptoms with each rechallenge suggests that some individuals may be sensitive. The only way to clearly determine this is through focused clinical studies. Because of the numbers of reports, the subtlety and potential seriousness of some of the manifestations, the concerns of some scientists, and the possibility that one complainant has had his symptoms of hyperactivity verified on independent exam, it would seem that the highest priority for any future investigations might be in the neurological/behavioral area, focusing on such symptoms as headaches, mood alterations, and behavior changes.

The report language accompanying this bill directs the FDA to ensure that these tests are undertaken.

At mark up, I proposed an amendment which would require the manufacturers of diet soft drinks to include on their label how much aspartame (NutraSweet) each serving contains.

I believe consumers have a right to this information given the questions which have been raised about NutraSweet and the extraordinary increase in consumption levels of this product since its

introduction in 1981 (last year per capita consumption increased 66%).

The National Soft Drink Association has lobbied strongly against this proposal. However, this is the same association which, in 1983, prepared a draft legal document objecting to NutraSweet's being allowed on the market, citing serious and unresolved questions about the public health. Though that document was not filed, it indicates the organization had significant health concerns relating to the amount of aspartame consumed before this product was approved for soft drinks. The following quotes are from a document entitled "Objections of the National Soft Drink Association to a Final Rule Permitting the Use of Aspartame in Carbonated Beverages and Carbonated Beverage Syrup Bases and a Request for a Hearing on the Objections." The document is dated August 8, 1983, and was prepared by Patton, Boggs and Blow and the General Counsel for the National Soft Drink Association:

"G. D. Searle and Company has not demonstrated to a reasonable certainty that the use of aspartame in soft drinks, without quantitative limitation, will not adversely affect human health as a result of the changes such use is likely to cause in brain chemistry and under certain reasonably anticipated conditions of use."

"For these reasons, Searle has not met its burden of demonstrating to a reasonable certainty that the unlimited use of aspartame, especially in combination with carbohydrates, will not adversely affect human health. The questions posed by Dr. Wurtman are significant because of the seriousness of the potential effects (e.g., changes in blood pressure) and because of aspartame's anticipated widespread use—use that includes consumption by potentially vulnerable sub-groups, such as children, pregnant women, and hypertensives."

"Specifically, Searle has not met its burdens under Section 409 . . . to demonstrate that aspartame is safe and functional for use in soft drinks."

"Collectively, the extensive deficiencies in the stability studies conducted by Searle to demonstrate that aspartame and its degradation products are safe in soft drinks intended to be sold in the United States, render those studies inadequate and unreliable."

There have been hundreds of reports from consumers around the country suggesting a possible relationship between their consumption of NutraSweet and subsequent symptoms including headaches, aberrational behavior, slurred speech, etc.

During the Labor Committee hearing on saccharin, NutraSweet, and cyclamate held on April 2, Dr. Richard Wurtman of M.I.T., testified as follows:

> The problem at present is that it is difficult if not impossible for the patient or his physician to know how much aspartame it contains . . . I believe it is essential that companies which include aspartame in their products be required to indicate on the labels (in readable print) how much of the sweetener is present in each can or serving. This simple change in labeling practice would, I believe, sharply reduce the number of consumers who believe without probable foundation that they have suffered aspar-

tame-related side-effects. Perhaps more importantly, it would also enable physicians to identify those patients who might really have had such responses, so that such people might then undergo controlled clinical testing.

Since 1981, the FDA has attached an ADI (acceptable maximum daily intake) to NutraSweet. That ADI is currently 50 milligrams per kilogram of body weight. While an adult weighing 154 pounds would not meet that limit before he consumed 5 liters of diet soft drink, a four-year-old weighing 25 pounds would hit that limit at three cans of diet soda. Consumers have no way of knowing if they have reached the FDA limit without knowing how much is in the can. Ideally, we should have the ADI on the can as well, but it will take some time to figure out how that could be done effectively. In the meantime we should ensure that the quantity is on the label. We must start somewhere, and this is an important first step.

Many questions must be resolved concerning aspartame. The FDA should take an active role to ensure that tests are conducted to determine whether individuals, particularly children, are likely to experience side-effects from NutraSweet at current and projected consumption levels. The FDA should also run tests on how NutraSweet affects those who might be taking different types of medication.

Finally, given the serious questions which remain regarding the FDA approval process for NutraSweet, the FDA should ensure that certain key pivotal animal tests are repeated. Only when all of these questions are resolved can consumers be certain that they are receiving the full protection provided by our food and drug laws.

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